

## REMARKS

Included herewith is an unexecuted copy of a second Declaration under Rule 132 by Dr. Jean Bousquet. This second Declaration merely corrects clerical errors in the first Declaration submitted with the applicant's previous response. An executed copy of this second Declaration will be submitted shortly.

### **Claim rejections under 35 U.S.C. § 103(a)**

The Office imposed two rejections under 35 U.S.C. § 103:

1. Claims 10, 22, 23, 25-28 were rejected under 35 U.S.C. 103(a) as being unpatentable over Gensthaler (*Pharmazeutische Zeitung*, vol. 146, no. 7, 2001-02-15, p. 35-36) in view of Scheinfeld (*J of Drugs in Dermatology*, Publication date 12/01/2002) and further in view of van Cauwenberge et al. (Applicants cited exhibit 4, Rule 132 declaration, 5/12/2008, Allergy, 2000, 55, 1 16-1 34). For the following reasons, the applicants respectfully traverse.
2. Claim 24 was rejected under 35 U.S.C. 103(a) as being unpatentable over Gensthaler (*Pharmazeutische Zeitung*, vol. 146, no. 7, 2001-02-15, p. 35-36) in view of Scheinfeld (*J of Drugs in Dermatology*, Publication date 12/01/2002) and further in view of van Cauwenberge et al. (Applicants cited exhibit 4, Rule 132 declaration, 5/12/2008, Allergy, 2000, 55, 1 16-1 34) as applied to claims 10, 22, 23, 25-28 above and further in view of Salmon et al. (US 200310236275).

For the following reasons, the applicants respectfully traverse.

In the previous Action, the Office rejected claims 10, 22, 23, and 25-28 over Gensthaler in view Leynadier. In the present Action, the Office has substituted Scheinfeld for Leynadier and included van Cauwenberge et al. for its alleged teaching of extend periods of treatment.

But Scheinfeld teaches nothing more of relevance to the present claims than Leynadier. The Office had relied on Leynadier for its teaching of the use of levocetirizine to treat SAR. The teachings of Scheinfeld relied upon by the Office differ only in that they relate to the use of levocetirizine to treat PAR. But as the applicants argued in their previous response and Dr. Bousquet demonstrated in his Rule 132 Declaration, results observed by treating SAR or PAR with levocetirizine are not reasonably predictive of the results that would be achieved by treating PER with levocetirizine.

The previous and present Office Actions seem to assume that because SAR, PAR, and PER all relate to allergic rhinitis and people suffering from these afflictions frequently are sensitive to similar allergens (e.g., dust mites), those of ordinary skill in the art would have expected that treatments used for SAR and/or PAR would be equally applicable to PER as well. But the Office has provided no evidence of this.

Moreover, the Rule 132 Declaration submitted by the applicants provides evidence and the reasoning of one of the world's leading experts on allergic rhinitis establishing why those of ordinary skill in the art would not and could not have reasonably extrapolated the results observed with SAR and/or PAR to PER.

Furthermore, other than broadly asserting that the Rule 132 was fully considered and found not persuasive, the Office has not addressed the Rule 132 Declaration. The Office has not explained why any of the evidence or reasoning supplied by Dr. Bousquet is faulty or inapposite. Rather, in the section entitled "Response to Arguments," the Office reiterates essentially the same arguments proffered as the basis for obviousness, which is that the prior art teaches the use of levocetirizine for the treatment of PAR (not PER) and that a portion of patients with PAR and those with PER are both sensitized to dust mites. The Office further adds that Webster's Dictionary defines "perennial" as "present all seasons of the year" or "persistent without interruption," implying that "perennial" and "persistent" are the same and, correspondingly, PAR and PER are as well.

There are at least two faults with the Office's reasoning. First, as noted in the previous paragraph, it is not a discussion of the evidence and reasoning supplied in Dr. Bousquet's Declaration. In fact, it ignores Dr. Bousquet's Declaration.

Second, the Office's reliance on the dictionary definition of "perennial" is contrary to established law. In the *en banc* Federal Circuit opinion in *Phillips v. AWH Corp.*, the court rejected reliance on dictionaries as a primary source of claim term meaning, reiterating that "a general-usage dictionary cannot overcome art-specific evidence of the meaning of a claim term." *Phillips v. AWH Corp.*, 75 USPQ2d 1321, 1333 (Fed. Cir. 2005) (*en banc*). In the present instance, the Rule 132 Declaration provides evidence both in the form of peer-reviewed journal articles as well as the opinion of one of the world's leading experts in allergic rhinitis that "perennial" and "persistent" are not and cannot be used interchangeably in the context of describing the afflictions known as perennial allergic rhinitis (PAR) and persistent allergic

rhinitis (PER). The Office's reliance on Webster's Dictionary is therefor misplaced and improper.

The Office admits that neither Gensthaler nor Scheinfeld teach administration for a period equal to more than 3 months (as recited in the presently pending claims) and relies on van Cauwenberge for its teaching of the use of a topical steroid for long term use of up to several months. But the applicants note that the long term use of a steroid is not a teaching or suggestion for long term use of an antihistamine, let alone the third generation non-sedative antihistamine levocetirizine. Indeed, rather than suggesting antihistamine treatment be extended for a period of several months if it is not successful after a shorter period of time, van Cauwenberge suggests using a topical steroid for several months instead. When faced with the problem of ineffectiveness with short term use of an antihistamine, rather than suggesting longer term treatment with the antihistamine, van Cauwenberge suggested using an entirely different class of drugs, topical steroids, rather than long term antihistamine use. Thus, it was plainly not obvious to van Cauwenberge et al. to use an antihistamine for an extended period.

In addition, van Cauwenberge's teachings are further distanced from the presently claimed method because they relate to PAR, not PER (as recited in the present claims).

Lastly, the applicants respectfully submit that their previous arguments and the evidence and reasoning in the Rule 132 Declaration of Dr. Bousquet are equally relevant and forceful against the present rejections, and the applicants maintain and reiterate them here by reference.

In brief:

1. SAR and PAR are recognized by those of ordinary skill in the art as being afflictions distinct from PER because they do not describe allergic rhinitis sufferers sharing a single or closely related set of etiologies. As Dr. Bousquet explains, "intermittent" and "persistent" are not synonymous with "seasonal" and "perennial".
2. Because of the art-recognized distinctions between SAR and PAR on the one hand and PER on the other, one of ordinary skill in the art could not have reasonably predicted that treatment of PER with levocetirizine for a period of at least 3-months (as presently claimed) would be effective based on results observed in the treatment of SAR and/or PAR.

The applicants respectfully submit that the Office has not presented any scientific evidence in support of its supposition that the results reported in Gensthaler, Scheinfeld, van Cauwenberge, and Salmun relating to PAR can be extended to PER. The only evidence of record

establishes that one of ordinary skill in the art at the priority date of the present application could not have reasonably predicted or expected that a patient suffering from PER could be successfully treated with Levocetirizine for a period of more than 3-months.

In view of the foregoing, therefore, the applicants respectfully submit that claims 10, 22, 23, 25-28 cannot be obvious over Gensthaler in view of Scheinfeld and further in view of van Cauwenberge et al., and that claim 24 is not obvious over Gensthaler in view of Scheinfeld and further in view of van Cauwenberge et al. as applied to claims 10, 22, 23, 25-28 above and further in view of Salmun et al. (US 200310236275). Accordingly, the applicants respectfully request withdrawal of the rejections based on 35 U.S.C. § 103.

If there are any questions or comments regarding this response or application, the Examiner is encouraged to contact the undersigned attorney as indicated below.

Respectfully submitted,

Date: November 6, 2008

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